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Shaughnessy No. 105501

Date Out EAB: 7/10/89

TO: Taylor/Giles
Product Manager 25
Registration Division (H7505C)

FROM: Patrick W. Holden, Chief
Ground-Water Technology Section
Environmental Fate & Ground Water Branch (H7507C)

THRU: Hank Jacoby, Acting Chief
Environmental Fate & Ground Water Branch (H7507C)

Attached please find the environmental fate review of:

Reg./File No.: _____

Chemical: Tebuthiuron

Type Product: Herbicide

Product Name: Spike and Graslan

Company Name: Eli Lilly and Company

Purpose: Response to letter from the registrant for tebuthiuron on ground-water monitoring study requirements.

ACTION CODE: 350

Date Received: 05-31-89 EFGWB # 90618

Date Completed: 07-07-89 Total Review Time: 0.5 day

Monitoring study requested: / X /

Monitoring study voluntarily conducted by registrant: /___/

Deferrals To: _____ Biological Effects Branch

_____ Science Integration and Policy Staff, EFED

_____ Non-Dietary Exposure Branch, HED

_____ Dietary Exposure Branch, HED

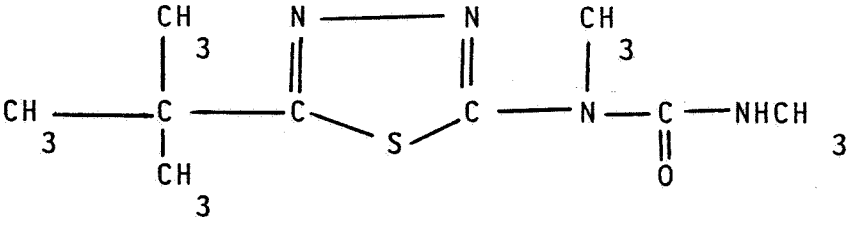
_____ Toxicology Branch, HED

1. Chemical:

Common name: Tebuthiuron

Chemical name: N-{5-(1,1-dimethyl)-1,3,4-thiadiazol-2-yl}-N,N'-dimethylurea

Structure:



2. Test Material:

Not applicable.

3. Study/Action Type:

This submission is a letter from the Eli Lilly and Company, registrant for tebuthiuron, regarding the data call-in requirement for a small-scale retrospective ground-water monitoring study. The letter asks for clarification on whether or not the toxicity of tebuthiuron is a consideration in the requirement of the ground-water monitoring studies. The letter is also a petition for OPP to reconsider our monitoring requirement prior to more extensive field dissipation work.

4. Study Identification:

Letter dated March 6, 1989 from Merlyn Jones to Edwin Tinsworth, record number: 245986, pack number: 49375.

5. Reviewed by:

Catherine Eiden, Acting Chief
Environmental Chemistry Assessment Section
Environmental Fate & Ground Water Branch

Catherine Eiden
7/7/89

6. Approved By:

Patrick Holden, Chief
Environmental Chemistry Assessment Section
Environmental Fate & Ground Water Branch

7. Conclusions:

The EFGWB concludes the monitoring study requirement should remain in place unchanged.

8. Recommendations:

The attached memorandum to Jay Ellenberger is a response to the exact same letter included with this submission. The memo explains EFGWB's position on the need for a ground-water study on tebuthiuron now. Please refer to this memo.

9. Background:

Tebuthiuron is used for total control of woody plants in noncropland areas, and brush and weed control.

10. Discussion of Individual Tests:

A. Study Identification:

Letter dated March 6, 1989, from Merlyn Jones to Edwin Tinsworth, record number: 245986, pack number: 49375.

B. Materials and Methods:

Not applicable.

C. Results:

Not applicable.

D/E. Conclusions:

Not applicable.

11. Completion of One-Liner:

No information from this submission has been added to the one-liner, as it contains no data.

12. CBI:

This submission contains no CBI.

MAY 16 1989

Eli Lilly and Company Letter dated 3-6-89
Concerning The Tebuthiuron Small-Scale
Retrospective Ground-Water Monitoring Study

Jay Ellenberger, Acting Chief
Generic Chemicals Support Branch (H7503C)
Special Review and Reregistration Division

Catherine Eiden, Acting Chief
Environmental Chemistry Assessment Section (H7507C)
Environmental Fate and Effects Division

Henry Jacoby, Acting Chief
Environmental Fate and Ground-Water Branch (H/507C)
Environmental Fate and Effects Division

Lilly and Company has been required to conduct a small-scale
rospective or prospective ground-water monitoring study
rough a data-call-in letter dated 5/4/88. Since receipt of
at letter, Eli Lilly and company has met twice with OPP on
/13/88 and 12/14/88 to discuss which type of study, if any, was
arranted.

Since this time, the company has agreed to conduct a small-scale
retrospective ground-water study, believing this type of study to
be more appropriate. However, as a result of the Scientific
Advisory Panel's (SAP) comments regarding the Standard
Evaluation Procedure for the Terrestrial Field Dissipation Study
(SEP), Eli Lilly and Company have requested postponing the
ground-water study until field dissipation data are submitted at
which time the data can be evaluated and the need for a ground-
water study determined.

The letter of 3/6/89 from Marlyn L. Jones also reiterates the
SAP's comment regarding the need to justify further field study
requirements because of the toxicological significance of
pesticide residues in soil at depth prior to initiating any
ground-water monitoring studies.

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The available environmental fate data on tebuthiuron clearly demonstrate that it is persistent and mobile. These criteria are indicative of a chemical that has a high potential to leach into the ground water. Further, the Agency has information that tebuthiuron has been positively detected in groundwater. Under these condition's for an older chemical, EFGWB's policy is to request a small-scale retrospective study in order to confirm movement through the soil profile into ground water for the detected chemical. To date, the need for a retrospective or a prospective study has not been premised on the toxicological significance or the moiety detected in ground water.

Once a small-scale retrospective or prospective study is carried out and the results indicate that a certain level of the pesticide's residues can, in fact, get into groundwater; then an assessment of the toxicological significance can be made for the purpose of regulation.

At this time, new field dissipation studies would require 2-3 years to complete. EFGWB does not think it is prudent to wait 2-3 years prior to initiating retrospective small-scale monitoring studies, for chemicals already detected in groundwater.

In conclusion, EFGWB concludes that a retrospective monitoring study is warranted. Eli Lilly and Company has selected a site in Corpus Christi, Texas. Our most recent meeting with Merlyn Jones was held 4/25/89, in which we discussed the site selected. Prior to study initiation, the company will finalize their study protocol and background site characterization. This one site will represent a normal use (pastureland) for tebuthiuron in a "relatively" worst-case setting.

cc: Anne Barton
Rick Tinsworth

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Plant Science Projects Development and Registration Division
Lilly Research Laboratories
Elanco Products Company
Divisions of Eli Lilly and Company

P.O. Box 708
Greenfield, Indiana 46140
Telephone (317) 467-4000

ELANCO

OCM
PATS

March 6, 1989

Mr. Edwin F. Tinsworth, Director
Special Review and Registration Division
Data Call-In Program
Registration Division (TS-767C)
Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

(PM-25) Mr. Taylor.

Dear Mr. Tinsworth:

RE: - TEBUTHIURON DATA CALL-IN NOTICE FOR SMALL SCALE RETROSPECTIVE GROUNDWATER MONITORING STUDY (EPA REG. NO. 1471-101)
- DATA CALL-IN OF MAY 24, 1988
- TEBUTHIURON GROUNDWATER CONFERENCE - SEPTEMBER 13, 1988
- TEBUTHIURON GROUNDWATER MEETING WITH CATHERINE EIDEN - DECEMBER 14, 1988
- RESPONSE TO FEBRUARY 13, 1989, LETTER REQUESTING COMMITMENT FOR GROUNDWATER RESEARCH

Lilly Research Laboratories of Eli Lilly and Company has been actively assessing the potential for conducting a small scale retrospective groundwater study for tebuthiuron. A small scale retrospective study was judged to be more appropriate than a prospective study after considering the points of discussion made at the September 13, 1988, meeting on this subject. We have identified a new site near Corpus Christi, Texas, that may satisfy the criteria for a groundwater study, using tebuthiuron on rangeland. This information was shared in a letter of January 6, 1989, to Ms. Geraldine Werdig plus I have continued to work directly with Ms. Catherine Eiden on our plans to further characterize this site..

At the same time, we continue to challenge the appropriateness of this study given the use claims for the product, its toxicology profile, research results from mobility studies, and field experience under actual use. Our position has been that a groundwater study is not appropriate unless soil dissipation studies indicate the need and then only if the toxicological significance of any residue is considered. On that point, tebuthiuron has no mammalian toxicology triggers according to recent EPA reviews and the life time health advisory for tebuthiuron has been set at over 400 µg/L.

This approach was supported by the Science Advisory Panel which recently reviewed a draft of the Standard Evaluation Procedure for Terrestrial Field Dissipation Studies. Not only would movement and detection of a pesticide at a 75-90 cm depth be required in appropriate field studies to justify going to the next tier of evaluations, they also stated that the residues should be of toxicological significance before additional studies are required. Three new comprehensive soil dissipation studies are being initiated this year on tebuthiuron that would provide guidance on the need for groundwater research, but results cannot be expected for several months.

In light of the Science Advisory Panels' recommendations and proposed guidelines, we petition you to reconsider the requirement to initiate a tebuthiuron groundwater study at this time. A groundwater study would be established if justified when results from existing soil dissipation studies are available and if the toxicological significance of given levels of tebuthiuron in groundwater justify further field evaluations.

At this time, further characterization of the proposed retrospective groundwater research site is proceeding and work is being scheduled to allow a 1989 trial initiation if required. Our strong preference, however, would be to delay initiation of this study until results from earlier tiers of research are available. Your earliest consideration of this matter is appreciated.

Sincerely,

ELANCO PRODUCTS COMPANY
A DIVISION OF ELI LILLY AND COMPANY

Merlyn L. Jones, Ph.D.
Project Manager
Plant Science Projects Development
and Registration Division

MLJ:aka

cc: C. A. Eiden (EPA)
R. J. Taylor (EPA)

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